UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
SIMS, JASON M

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1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	09/981,248	HOFFMAN ET AL.
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>26 June 2009</u>.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>25-30, 55-60, 85-89, and 91-93</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>25-30,55-60,85-89 and 91-93</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 6/26/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 6/26/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claim 93 in the response filed 6/26/2009, which is acknowledged and has been entered.

Claims 25-30, 55-60, 85-89, and 91-93 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, filed 6/26/2009, with respect to rejections of claims under 35 USC 112 First Paragraph have been fully considered and are persuasive because of applicant's amendments to the claims and arguments. Therefore the rejections have been withdrawn.

Claim Rejections - 35 USC § 101-Maintained in part

Response to Arguments

Applicant's arguments, filed 6/26/2009, with respect to rejections of claims 25-30 and 91-91 under 35 USC 101 as reading on non-statutory subject matter have been fully considered and are persuasive because of applicant's amendments to the claims and arguments. Therefore the rejection has been withdrawn.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 85-89 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 85-89 are drawn to a computer program on computer storage media media. A review of the specification does not show a definition of computer readable media such that excludes an embodiment that is information in a signal. For example, paragraph [0026] of the published application recites computer storage media "includes, but is not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks (DVD), or other optical disk storage, magnetic cassettes, magnetic tape, magnetic disk storage, or other magnetic storage devices, or *any other medium which can be used to store the desired information* and which can be accessed by server 22." Thus wireless communication such as a carrier wave reads on the "other medium which can be used to store the desired information" and causes said claims to being drawn to non-statutory subject matter. As such an embodiment of the claims read on non-statutory subject matter (In re Nuijten 84 USPQ2d 1495 (2007)).

Response to Arguments:

Applicant's arguments filed 6/26/2009 with respect to the rejection of claims 85-89 have been fully considered but they are not persuasive.

Applicant argues that storage media is directed toward tangible embodiments, thus causing said claims to being drawn to statutory subject matter.

Applicant's arguments are not found persuasive as paragraph [0026] of the published application recites "computer storage media includes, but is not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks (DVD), or other optical disk storage, magnetic cassettes, magnetic tape, magnetic disk storage, or other magnetic storage devices, or ***any other medium which can be used to store the desired information*** and which can be accessed by server 22." Thus wireless communication such as a carrier wave reads on the "other medium which can be used to store the desired information" and causes said claims to being drawn to non-statutory subject matter. A carrier wave is capable of carrying, i.e. embodying, such computer-executable instructions. Therefore, claims 85-89 remain drawn to non-statutory subject matter.

The following rejection has been modified, which was necessitated by amendment:

Claim Rejections - 35 USC § 103-Maintained/Modified

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-30, 55-60, 85-89 and 91-93 are rejected under 35 U.S.C. 103(a) as

being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp.

523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491)

and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000) and further in view of Fey

et al. (US Pub. 2002/0038227, filed 2/26/01) and further in view of Hogan (US A/N

2002/0110823).

Claims 25, 55, 85 and 91 are directed to a computer-implemented method for

processing hereditary data, and to a computer system and medium comprising

instructions or components for performing the method, wherein the method comprises

receiving a genetic test result value for a person, querying a computerized table listing

polymorphism values and atypical clinical events associated with h polymorphism

values, determining if the genetic test result value is a polymorphism value associated

with an atypical clinical event, and if so, accessing a list of risk-associated agents, and

outputting an "interpretation" of the genetic test result value and the list of risk-

associated agents. Claims 26, 56, 86 and 91 further limit the method to comprise

determining if a patient has been exposed to a risk-associated agent. Claims 27, 57,

and 87 limit the method to further comprise accessing an electronic medical record.

Claims 29-30, 59-60 and 89-90 limit the method to comprise initiating a clinical action if

a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent. Claim 93 limits the method to comprise determining whether to authorize in accordance with cost of the genetic test, a likelihood of a genetic variation based on demographic information of the patient and either automatically or through the physician ordering the genetic test.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathioprine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). ICHIKAWA does not specifically teach querying a computerized table listing polymorphism values and atypical events associated with the polymorphism values, electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with "idiosyncratic" drug reactions or altered drug sensitivity (p. 489, Table 1), thus teaching a list of "risk-associated agents". EVANS teaches that his Table 1 is a computerized table of atypical clinical events associated

with polymorphism values (see the legend for Table 1 which states "A comprehensive

listing is available at www.sciencemag.org/feature/data/104449.shl"). It is noted that

Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught

by ICHIKAWA. It is further noted that the table of EVANS contains many of the genes,

polymorphic sites, and atypical events disclosed by the instant specification in Table 2

on page 16. EVANS also teaches automated systems to associate an individual's

genotype with polymorphic genes in order to optimize drug administration and disease

treatment (p. 490, right column). EVANS does not specifically teach accessing an

electronic medical record.

REINHOFF teaches a computer-implemented method, and a system and

computer-readable medium comprising instructions for performing the method, wherein

information with regard to a patient's polymorphic profile is linked to a degree of

response of the patient to a treatment, specifically to side effects; i.e. an "atypical"

clinical response (paragraphs 33, 38, 57 and 59). Specifically, REINHOFF teaches

populating a computerized database with genotypic and phenotypic data (para 38) and

teaches that polymorphic profiles of individuals may be associated with response to

drugs in a computerized method (para 57). He further teaches analysis of such data in a

computerized database (para 58), thus teaching a step of "querying" a computerized

listing comprising polymorphic data and atypical clinical events associated with the

polymorphic data. REINHOFF also teaches that a variety of electronic medical and/or

clinical records may be accessed in his method (paragraph 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by REINHOFF, and to have accessed/queried a computerized list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59) and/or to determine an appropriate dosage of the agent, as taught by REINHOFF (paragraph 57) and ICHIKAWA (p. 523, left column, last paragraph).

REINHOFF suggests, but does not explicitly recite a graphical user interface having specific functionality.

REINHOFF suggests this because REINHOFF teaches, at paragraph [0040] computers running customized software supporting the service provided by the taught invention, wherein it is common for software to have built in GUIs for easier functionality for a user. Furthermore, REINHOFF teaches at paragraph [0010] that the computer program product allows identification of a susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain disease, i.e. it is commonly understood wherein a doctor would perform the risk assessment thereby implying that the networked system comprising the program product is intended not just for patients, but also doctors or hospitals.

Fey et al. teach at paragraphs [0022] [0048] and [0055] an application of health data management which involves a graphical user interface written for web browser

applications wherein the user has a unique identification and may enter information

through the GUI. Fey et al. at paragraph [0012] teach keeping secure health records,

which are accessible by authorized health persons. Fey et al. further teach that custom

reports are generated at the time tests are performed that explains the results. Fey et

al. teach at paragraph [0022] wherein results are prepared for the individual and

physician. Fey et al. teach at paragraph [0047] wherein the health data may be used by

doctors. In addition, Fey et al. at paragraphs [0053] – [0059] and [0063] – [0075] teach

a system comprising a means, i.e. a displaying component and computer storage media

configured for displaying a graphical user interface as in claims 55 and 85. With further

regards to claim 85, Fey et al. teach at paragraph [0031] storing the genetic test results.

Fey et al. does not explicitly teach a GUI that is configured to solicit input from a

clinician to ascertain whether to authorize performing a genetic test on a patient. In fact,

Fey et al. teach, i.e. paragraph [0057] that the invention is directed to enabling a

client/consumer to order genetic testing without doctor's approval. Furthermore, Fey et

al. teach that a client can use the taught invention to determine genetic risk towards

disease or conditions or discover genetic predispositions.

Although it appears that the invention of Fey et al. does not actually teach a

physician based system, it is the functionality of said system, which is taught that is the

focus. The invention taught by Fey et al. has the functionality of using a graphical user

interface to solicit input, albeit a client, to ascertain whether to perform a genetic test,

displays identification of the genetic test to be performed, receives approval or

authorization from the client to carry out the genetic test, ensures identification of the person, and is configured to receive result value of the genetic test for the person.

Hogan at the abstract discusses a method for tailoring a subject's surgical treatment to reflect genetic information. Hogan at paragraph [0005] discusses that the choice of anesthetic regimen, agent, and dose depends on the type of surgery or procedure. Hogan at paragraphs [0011] – [0013] discusses genomic screening of a subject prior or during a surgical procedure to obtain a genomic profile. Hogan at paragraphs [0019] – [0022] discusses obtaining a genomic profile for a subject which screens the subject for one or more polymorphism values associated with one or more clinical events associated with one or more clinical agents. Hogan at paragraphs [0018] and [0019] discusses screening a patient to determine a risk for surgical complications associated with known genetic variations. Furthermore, Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor, which reads on displaying to the clinician a list of risk-associated agents, a warning of the effects of the polymorphism value, and alternate clinical agents that are not associated with the polymorphism value.

Additionally, Hogan at paragraph [0187] they teach a set of criteria to be met prior to administering a genetic test or genomic profile test, such as whether the subject is a candidate for genomic profiling, if a particular method is available for performing said test, if the method will provide useful information for a particular application and its practicality, and if there is clinical utility, i.e. provide a predication of a phenotype related to the genotype. Hogan at paragraphs [0005], [0008], and [0138] discusses assessing

the dosages associated with the clinical agents and risk assessments. Hogan at

paragraphs [0186] and [0188] – [0193] discusses that the clinical agent and genetic

information may be stored and communicated via various computerized applications,

including electronic medical records including computers. Hogan at paragraph [0031] –

[0033] discusses a problem is "how to alter treatment course of action in response to

results," as in genomic screening results and the present invention unites "medicine with

genetics" to solve the described problem and to individualize treatment options for each

subject. Hogan at paragraphs [0190] – [0191] teaches outputting information about the

atypical clinical event associated with the polymorphism values such that a "clinical

action" may be initiated. Hogan at paragraph [0190] discusses that the risk assessment

for the various treatment options are displayed to the clinician on a computer monitor.

Furthermore, Hogan at paragraphs [0115], [0129], [0136] – [0147], and [0186] teaches

comparing genetic test result values for multiple genes to polymorphoism values

associated with adverse reactions, i.e. risks associated with atypical clinical events, and

that agent information may include dosage and other PK/PD parameters.

It would have been obvious to one of ordinary skill in the art at the time of the

instant invention to have used the system for authorizing genetic tests and displaying

results, etc. as taught by Fey et al. and Hogan for use by a physician as taught by

REINHOFF, ICHIKAWA and EVANS. This is because REINHOFF teaches a program

product for studying genetic data and using genetic screening methods to assess

increased risk of certain diseases and conduct basic research on population genetics. It

would have been obvious to the skilled artisan to improve the invention of REINHOFF

by adding a secured health data management system, wherein a physician can

ascertain whether to authorize performing a genetic test on a patient based on their

assessed risk for a certain disease. REINHOFF teaches at paragraphs [0008] – [0009]

using a web system to create polymorphic profiles for individuals. Therefore, creating a

secured health data management system wherein the polymorphic profiles are stored

and further genetic tests can be authorized as deemed necessary can be seen as an

improvement wherein the results would be predictable. Moreover, a skilled artisan

would find that the differences between the claimed invention and the prior art were

encompassed in known variations or in a principal known in the prior art.

    Fey et al. does not explicitly teach automatically scheduling counseling for the

person, automatically ordering follow-up tests, nor automatically providing a notification

in an email address to a physician that informs the physician to no longer administer the

agent, wherein the physician is identified by the person's electronic medical record.

    However, Fey et al. teach at paragraph [0042] generating custom reports of the

genetic tests. Fey et al. further teach at paragraph [0044] the data is analyzed in

conjunction with known medical data, such as disease, risk factors, screening factors,

etc. Fey et al. at paragraph [0045] teach that the personalized health record reviews

health risks and thoroughly explains test results with follow-up recommendations and

determine further health risks.

    It would have been obvious to one of ordinary skill in the art at the time of the

instant invention to have automated particular follow-up recommendations such as

ordering another genetic test based on a health record or sending an email message to

discontinue the administration of a particular drug with known adverse effects on the client with a particular genetic predisposition in the method of Ichikawa, Reinhoff, Evans, Fey and Hogan.   This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result to a physician indicating an adverse effect of a particular drug being taken would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents as in claim 91.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have have ascertained a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative

order for an agent that is absent from the list of risk-associated agents when generating

the follow-up recommendations as taught by Fey et al..   This is because the goal of the

health data management system is to enable a consumer/client to better monitor their

health at a genetic level and monitor their potential health risks based on genetic

screening. Therefore, an automated result ascertaining a low-risk or high-risk clinical

response based on whether the person has been exposed to an agent on a list of risk-

associated agents; if the person has been exposed, automatically generating the high-

risk clinical response that includes suspending an order for the agent and placing an

alternative order for an agent that is absent from the list of risk-associated agents, when

generating the follow-up recommendations as taught by Fey et al would be seen as an

obvious improvement to the health management system where the results would have

been predictable to one of ordinary skill in the art. Furthermore, automation of known

methods, such as further automating the automated follow-up recommendations would

be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. teach at paragraphs [0019] and [0049] that the medical records are

accessible and updating the healthcare system, wherein updating integrates heredity

data with newfound knowledge as in claim 86.

With regards to claim 93, Hogan at paragraph [0187] teaches information generated by

perioperative genomic profiling is automated.   Hogan at paragraph [0187] they teach a

set of criteria to be met prior to administering a genetic test or genomic profile test, such

as whether the subject is a candidate for genomic profiling, if a particular method is

available for performing said test, if the method will provide useful information for a

particular application and its practicality, and if there is clinical utility, i.e. provide a

predication of a phenotype related to the genotype. Hogan at the background and

paragraphs [0030] – [0034] discuss the cost-effectiveness and importance of it when

performing perioperative testing of patients, i.e. genomic profiling. Furthermore, at

paragraphs [0119] – [0127] Hogan teaches that only markers that correlate with a

subject's response or ones that can provide effective and helpful information are

included in obtaining a genomic profile. Hogan at paragraph [0031] – [0033] discusses

a problem is "how to alter treatment course of action in response to results," as in

genomic screening results and the present invention unites "medicine with genetics" to

solve the described problem and to individualize treatment options for each subject.

Thus, Ichikawa, Reinhoff, Evans, Fey and Hogan make the claimed invention obvious.

Response to Arguments

Applicant's arguments filed 6/26/2009 have been fully considered but they are

not persuasive.

Applicant summarizes claim amendments from pages 9-11 in the arguments. At

page 12, applicant argues that Reinhoff do not describe automatically generating a

notification window that displays a list of risk-associated agents, warning of effects of

the polymorphism value, or alternate clinical agents not associated with the

polymorphism value.

Applicant's arguments are not found persuasive because it was stated in the

Office Action that Reinhoff do not explicitly teach the recited specific functionality of the

GUI, and that Fey teaches the specific functionality of the GUI, which is reiterated as

follows:

> "REINHOFF suggests, but does not explicitly recite a graphical user interface having
> specific functionality.
>
> REINHOFF suggests this because REINHOFF teaches, at paragraph [0040] computers
> running customized software supporting the service provided by the taught invention, wherein it is
> common for software to have built in GUIs for easier functionality for a user. Furthermore,
> REINHOFF teaches at paragraph [0010] that the computer program product allows identification
> of a susceptibility locus in individuals using genetic screening methods to assess an individual's
> risk of certain disease, i.e. it is commonly understood wherein a doctor would perform the risk
> assessment thereby implying that the networked system comprising the program product is
> intended not just for patients, but also doctors or hospitals.
>
> Fey et al. teach at paragraphs [0022] [0048] and [0055] an application of health data
> management which involves a **graphical user interface** written for web browser applications
> wherein the user has a unique identification and may enter information through the GUI. Fey et
> al. at paragraph [0012] teach keeping secure health records, which are accessible by authorized
> health persons. Fey et al. further teach that custom reports are generated at the time tests are
> performed that explains the results. Fey et al. teach at paragraph [0022] wherein results are
> prepared for the individual and physician. Fey et al. teach at paragraph [0047] wherein the health
> data may be used by doctors. In addition, Fey et al. at paragraphs [0053] – [0059] and [0063] –
> [0075] teach a system comprising a means, i.e. a displaying component and computer storage
> media configured for displaying a graphical user interface as in claims 55 and 85. With further
> regards to claim 85, Fey et al. teach at paragraph [0031] storing the genetic test results.
>
> Fey et al. does not explicitly teach a GUI that is configured to solicit input from a clinician
> to ascertain whether to authorize performing a genetic test on a patient. In fact, Fey et al. teach,
> i.e. paragraph [0057] that the invention is directed to enabling a client/consumer to order genetic

testing without doctor's approval. Furthermore, Fey et al. teach that a client can use the taught invention to determine genetic risk towards disease or conditions or discover genetic predispositions.

Although it appears that the invention of Fey et al. does not teach a physician based system, it is the functionality of said system, which is taught that is the focus. The invention taught by Fey et al. has the functionality of using a graphical user interface to solicit input, albeit a client, to ascertain whether to perform a genetic test, displays identification of the genetic test to be performed, receives approval or authorization from the client to carry out the genetic test, ensures identification of the person, and is configured to receive result value of the genetic test for the person.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the system for authorizing genetic tests and displaying results, etc. as taught by Fey et al. for use by a physician as taught by ICHIKAWA, REINHOFF, and EVANS. This is because REINHOFF teaches a program product for studying genetic data and using genetic screening methods to assess increased risk of certain diseases and conduct basic research on population genetics. It would have been obvious to the skilled artisan to improve the invention of REINHOFF by adding a secured health data management system, wherein a physician can ascertain whether to authorize performing a genetic test on a patient based on their assessed risk for a certain disease. REINHOFF teaches at paragraphs [0008] – [0009] using a web system to create polymorphic profiles for individuals. Therefore, creating a secured health data management system wherein the polymorphic profiles are stored and further genetic tests can be authorized as deemed necessary can be seen as an improvement wherein the results would be predictable. Moreover, a skilled artisan would find that the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

Applicant further argues that at the time of the invention doctors were not knowledgeable of the effects of a person's genetic disposition on the treatment and what alternatives to each course of treatment would comprise.

Applicant's arguments are not found persuasive as ICHIKAWA teaches prior to the instant invention that it was known that a person's genetic disposition has effects on the treatments and alternatives to the course of treatment.

Applicant further argues that Fey does not describe automatically generating a GUI with a notification window that displays a list of risk-associated agents, warning of effects of polymorphism value, or alternate clinical agents that are not associated with the polymorphism value.

Applicant's arguments are not found persuasive because in the instant rejection it is the Hogan reference cited for teaching said limitations.

Applicant further argues that none of the cited portions of the references teach reviewing two criteria, (a) a cost of the genetic test, and (b) a likelihood of a genetic variation based on patient information.

Applicant's arguments are not found persuasive as it is stated in the instant Office Action that the Hogan reference considers these two criteria.

Applicant further argues at page 15 that none of the cited references teach or suggest a decision tree that looks at a genetic test result value, personal information, and background information.

Applicant's arguments are not found persuasive as the combination of references now including the Hogan reference look at all three criteria as stated above.

Applicant further argues at page 16 that none of the cited references teach or

suggest looking at both the identity of the agent and the dosage of the agent to

determine a clinical response, which includes adjusting the dosage.

Applicant's arguments are not found persuasive as the Hogan reference teaches

this very limitation as discussed in the office action above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

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